Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12979

0 - FRONT

CFSAN

Individual Safety Report

3093449-3-00

85028 12979

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTAR
by health professional
events and product

Page ___ of _

A. Patient Information

1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	[redacted]	☒ female ☐ male	173 lbs or ___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 5/14/96

4. Date of this report (mo/day/yr): 5/19/96

5. Describe event or problem

No hx of hypertension
Devel mod/severe
HTN & tachycardia

RECEIVED
JUN 19 1998

6. Relevant tests/laboratory data, including dates

BP 168/104
P: 100

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Healthy

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Metabolife 1-888-356-Diet
#2

2. Dose, frequency & route used
#1 1 PO QID
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 discontinued 5/10
#2

4. Diagnosis for use (indication)
#1 wt loss/obesity
#2

5. Event abated after use stopped or dose reduced
#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
added Procardia to ↓ HR & BP

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address
REC'D.
JUN 16 1998
MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6. model # ___
catalog # ___
serial # ___
lot # ___
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address [redacted] phone # [redacted]

000001

2. Health professional? ☒ yes ☐ no

3. Occupation: Physician

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

PLEASE TYPE OR USE BLACK INK

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (6/98)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

85028

Adverse Reaction Questionnaire

Complaint Number: CFSAN Project# 12979 Investigator: Joan T. Briones

Consumer Information

Date of Report: 05/19/98 (MM/DD/YY)

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 61

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 05/14/98
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home & office.

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Difficulty sleeping, "night sweats" - did not notice a correlation with product consumption and symptoms.

How long did the symptoms last? ~ 1 month.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
1-6 capsules a day for ~ 1 month.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
No other products used.

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☒Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? See records.

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

000002

Product Category

Adverse reaction to:

☐ Medical Food (under medical supervision) ☐ Infant Formula

☒ Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)

☐ Other (traditional food) _____

Other Product Problems

2. ☐ Foreign Object (specify): _____

3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

See label.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

See label.

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐ Aspartame
☐ Monosodium Glutamate
☐ Sulfite
☐ Other_____
☐ Unknown

☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒ Yes ☐ No ☐ Unknown

Product Sample Available: ☐ Yes ☒ No ☐ Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☐ Yes ☒ No

000003

Hospitalization: ☐ Yes ☒ No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐ Yes ☒ No

Did the adverse reaction result in a congenital anomaly: ☐ Yes ☒ No

RECEIVED
CLINICAL RESEARCH
REVIEW/OSN HFS-452
86 OCT -6 P2:36

ARMS# 12979

[redacted]

[redacted]

September 11, 1998

Attention: Joan Briones
Department of Health and Human Services
FDA Sacramento Resident Post
801 I Street, Room 443
Sacramento, CA 95814

Dear Ms. Briones:

Included with this letter are copies of chart notes regarding the two patients with adverse outcome secondary to MetaboLife. They have both agreed to be contacted.

The first patient is [redacted] whose phone number is [redacted]. The second patient is [redacted] and she can be reached at [redacted]

I hope the FDA can be of some help in getting this product off the market. It is very heavily advertised in our area and since my complaints to the FDA, I have seen several other patients with tachycardia secondary to this product. If you have any questions please call me at [redacted] Thank you for your help.

Sincerely,

[redacted]

[redacted] M.D.

CFSAN PROJECT #s 12978, 12979
SAN TRAK3 # 98-1432
JTB
Exhibit 1, 1 of 1

000004

Memorandum of Record

To: Lori A. Love, M.D.

From: Constance J. Hardy, M.S., R.D.

Date: March 1, 1999 and June 9, 1999

Subject: ARMS #12979
Follow-up with consumer

I spoke with the consumer, [redacted] on two occasions to obtain additional information regarding her frequency and duration of use of the product, Metabolife 356, as well as additional information about her symptoms. Ms. [redacted] stated that she had been taking Metabolife for about 3 weeks, perhaps slightly longer. She had discontinued it 4 days before seeing Dr [redacted] but saw him anyway because a co-worker had measured her blood pressure and had found it to be elevated. She stated that she took no more than 2 capsules of Metabolife at a time. She stated that for the first 2 weeks, she usually took only 1 - 2 capsules per day. She had increased her dose of Metabolife to 4 - 5 capsules per day (no more than 2 at a time), but that she had done this for no more than 3 or 4 days. All during this time she had experienced a "heaviness" in her chest, but she did not mention it to Dr. [redacted] because she attributed it to her asthma. She verified an inability to sleep, but, at the time of the interview on June 9, 1999, was unable to remember whether she had had night sweats prior to stopping the product.

Ms. [redacted] stated that at the time of her visit with Dr. [redacted] on June 22, 1998, he had told her that she had had a "heart attack." She subsequently underwent bypass surgery. Her current medications include Atenolol, aspirin, Lipitor, and Allegra.

She has agreed to sign an authorization for release of medical records.

TO: Lori Love, M.D., Nancy Slifman, M.D.,
CRRS

FROM: Constance J. Hardy
DPEP

DATE: 5/27/99

SUBJECT: ARMS 12979

I verified with Ms. [redacted] that the consumer [redacted] was in Dr. [redacted] office on May 14, 1998 and not on May 15, 1998, as stamped on the initial vital signs sheet. She stated that sometimes in the late afternoon the next day's vital sign sheets are date stamped. She surmised that this is possibly the reason why there is a discrepancy with the dates. She verified that Dr. [redacted] notes pertaining to blood pressure are different than those noted on the handwritten sheet date stamped May 15, 1998. This is because he commonly measures blood pressure readings upon seeing a patient, even though the blood pressure may have previously been taken.

File name: [redacted]